



Robert C. Byrd
National Technology Transfer Center
at Wheeling Jesuit University

March 31, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852

Dear Dr. Rohrbaugh:

I recently became aware of a petition addressed to you by Mr. James Love, President of Essential Inventions, Inc. requesting that the National Institutes of Health exercise the march-in rights provision of the Bayh-Dole Act to lower the price of several drugs developed from NIH extramural research.

While the subject of delivering affordable health care is certainly a serious issue, the provisions of the Bayh-Dole Act do not provide for governmental actions such as those requested by Essential Inventions. Indeed, such actions were never contemplated by the Congress and are not reflected in the legislative history of the law.

The interpretation of the intent of Congress in passing this landmark legislation reflected in Mr. Love's petition is, therefore, entirely fanciful.

While serving former Senator Birch Bayh on the Senate Judiciary Committee, I staffed the hearings and wrote the report of the Senate Judiciary Committee on the bill. I also served for many years as the Director of Technology Commercialization at the U.S. Department of Commerce. There I oversaw the implementation of the regulations for Bayh-Dole and chaired the Interagency Committee on Technology Transfer which developed guidelines for utilizing the Federal Technology Transfer Act, under whose authorities NIH develops many of its intramural partnerships with U.S. industry.

Regrettably, Mr. Love and several others making the same case mix up the legislative history of the Bayh-Dole Act with hearings on rival legislation that was not enacted. The **only** legislative history with any bearing on the law are the hearings of the U.S. Senate Judiciary Committee in the 96th Congress on S. 414, the University and Small Business Patent Procedures Act (commonly called Bayh-Dole), the report of the Senate Judiciary Committee on the same, and the Senate debates on S. 414.

Fortunately, we do have an unambiguous opinion from Senators Birch Bayh and Robert Dole themselves on the topic at hand. The *Washington Post* ran an article by Professors Peter Arno and Michael Davis on March 27, 2002, **Paying Twice for the Same Drugs**, making the same arguments as Mr. Love. They wrote:

Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and, if refused, license it to third parties that will make the drug available at a reasonable cost.

A joint letter by Senators Bayh and Dole on April 11, 2002, to *The Washington Post* effectively refutes this argument. Here is the complete text of what the authors of the law said was their intent with regard to fair pricing of resulting products:

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every \$1 spent in government research on a project, at least \$10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

The article also mischaracterized the rights retained by government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a

company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. (Emphasis added).

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

Birch Bayh/Bob Dole

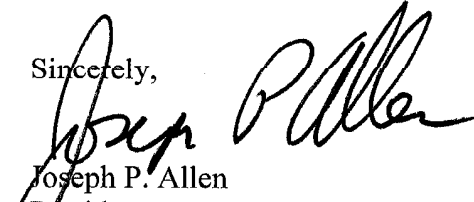
In their typically succinct manner, the authors of the law effectively rebut the argument now before you.

The Bayh-Dole Act has become a linchpin of our economy. While not perfect, the U.S. record of commercializing new products and services funded by the Government is the envy of the world. **The Economist Technology Quarterly** said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980." Any legislative or administrative actions undertaken to alter this Act must be done very carefully.

We have already witnessed well intended Congressional attempts to impose fair pricing clauses on NIH intramural research partnerships. These efforts failed. Technology transfer cannot be a vehicle for trying to control prices. Rather than allowing Government to dictate drug prices, companies simply walked away from partnering with NIH. Wisely recognizing its mistake, Congress rescinded the fair pricing requirement. NIH's subsequent success in building effective partnerships with industry is well documented, and is a great benefit to the public.

President Johnson asked in 1968 how many NIH owned inventions had been commercialized. The answer was none. At that time there were no incentives for industry to undertake the risk and expense inherent in developing such early stage inventions. We should reflect that because of the Bayh-Dole Act, many life saving drugs and therapies are now available for those in need. By altering this delicately balanced law, we may well discover that publicly funded inventions go back to gathering dust on the shelves. Before Bayh-Dole such discoveries were not available at any price.

Sincerely,



Joseph P. Allen
President
National Technology Transfer Center